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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,738	02/07/2006	Nikolay Khanzhin	429-US-PCT	4289

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LUNDBECK RESEARCH USA, INC.
ATTENTION: STEPHEN G. KALINCHAK, LEGAL
215 COLLEGE ROAD
PARAMUS, NJ 07652

EXAMINER

CHU, YONG LIANG

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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07/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,738	Applicant(s) KHANZHIN ET AL.	
	Examiner YONG CHU	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/23/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 5,8,9,11,13,14,16,19,20 and 24-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,7,10,12,15,17,18 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 1-4, 6-7, 10, 12, 15, 17-18 and 21-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

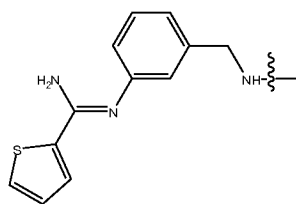
DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission on 04/23/2009 has been entered. Upon entering the submission, claims 1-37 are currently pending in the instant application. Claims 5, 8-9, 11, 13-14, 16, 19-20 and 24-37 remain withdrawn as non-elected subject matter.

Response to RCE Submission

Claim rejection under 35 U.S.C. §102(b)

Applicants' amendment by further limiting the optional substituent on an **Ar** or **Ar**-containing group of **R¹²** and **R^{12'}** has overcome the rejection. However, claim 1 is still remained rejected under 102(b) by the same previously cited '190 compounds, because **R³** is subject to multiple interpretation, wherein **R³** is interpreted as an optionally



substituted C₁₋₆alkyl group. The substituent is . The instant specification at paragraph [0426] does not define the alkyl as non-substituted alkyl, instead with some not limited examples. To overcome this rejection, Applicants need to clear define the alkyl is unsubstituted alkyl group.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-7, 10, 12, 15, 17-18, 21, and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the newly added limitation at page 3 of claim 1 does not have support in the original disclosure as follow:

the optional substituent on an Ar or Ar-containing group of R^{12} and $R^{12'}$ is independently selected from the group consisting of hydroxy, halogen, C_{1-6} -alk(en/yn)yl, C_{3-6} -cycloalk(en)yl, C_{3-6} -cycloalk(en)yl- C_{1-6} -alk(en/yn)yl, halo- C_{1-6} -alk(en/yn)yl, C_{1-6} -alk(en/yn)yl-oxy, C_{3-6} -alk(en/yn)yl-oxy, acyl, nitro, cyano, -CO-NH- C_{1-6} -alk(en/yn)yl, -CO-N(C_{1-6} -alk(en/yn)yl)₂, -NH₂, -NH- C_{1-6} -alk(en/yn)yl, -N(C_{1-6} -alk(en/yn)yl)₂, -S- C_{1-6} -alk(en/yn)yl, -SO₂- C_{1-6} -alk(en/yn)yl, -SO₂N(C_{1-6} -alk(en/yn)yl)₂ and SO₂NH- C_{1-6} -alk(en/yn)yl;

". To

overcome this rejection, Applicants need to either point out the support in the original disclosure for such amendment or cancelled the added limitation.

Claim Rejections - 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

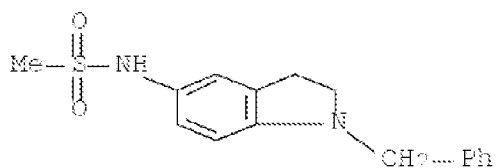
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6-7, 10, 12, 15, 17-18 and 21-23 are rejected under 35 U.S.C. 103 (a) as being unpatentable over WO2003031409 ("the '409 publication") by Cho et al. with publication date 04/17/2003 and PCT filing date 10/02/2002.

Determination of the scope and content of the prior art (MPEP §2141.01)

The '409 publication discloses a specific compound (CAS RN 512787-53-0)



as a pharmaceutical agent. This compound is related to the instantly elected scope of invention, wherein R^3 is alkyl; q is 0; X is SO_2 ; s is 0; R^2 is -H; R^1 and $R^{1'}$ is -H; Y is phenyl.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '409 compound and the instantly claimed compounds is the substituent on Y as a phenyl group, wherein the unsubstituted phenyl

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is excluded by the proviso of the second compound at the last paragraph of claim 1, which is N-[2,3-dihydro-1-(phenylmethyl)-1H-indol-5-yl]-methanesulfonamide. But claim 1



does not exclude **Y** as **Y**, wherein R^5 is $-CH_3$, and **f** is 1.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

To those skilled in the medicinal chemistry art, the prior art '410 compound renders the instantly claimed compounds obvious, because the difference is substituents on the **Y** phenyl ring as **Ar¹** as hydrogen vs. methyl. Both instant application and the prior art teach compounds used for pharmaceutical application, which are at the same endeavor. For one ordinary skilled in the art, methyl phenyl group and phenyl group is obviousness, In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978). Because knowing properties of one member of series compounds would in general know what to expect in adjacent members. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. pharmacological use). Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Conclusion

No claims are allowed.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu, Ph.D. whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu/
Patent Examiner
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